REMARKS

Claims 37-56 are pending. Claims 40-56 were withdrawn from consideration, leaving claims 37-39 subject to examination. Claims 37-39 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. In particular, claim 39 was rejected for omitting what the Examiner considers to be essential steps, while claim 37 was rejected due to a lack of antecedent basis for the term "CFP peptides" in the third line. The rejections are addressed by the amendments set forth above and the following remarks.

Applicants first thank the Examiner for the helpful interview of August 11, 2009, during which amendments to place claims 37 and 38 into condition for allowance were discussed, as well as the possibility of rejoinder of claim 39 and a kit claim of the scope of claim 37.

With respect to the rejection of claim 37, Applicants note that this claim has been amended according to the suggestion of the Examiner. In particular, the last two lines of claim 37 have been changed to "...wherein said peptide composition comprises a pool of CFP-10 peptides which consists of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, and SEQ ID NO: 8."

In response to the rejection of claim 39, Applicants note that this claim has been amended to include steps relating to detection and correlation, which the Examiner indicated were missing.

Step i) of claim 39 concerns admixing of whole blood or PBMC with a peptide composition. Support for this step is found, for example, in claim 39 as filed.

Step ii) of claim 39 concerns the collection of output data and analysis of this data to determine whether T-lymphocytes in the whole blood or PBMC have been activated or not by the admixed peptide composition. This analysis is carried out using common general knowledge of statistical analysis, consistent with the outline depicted in the flow chart of Fig. 9. Such analysis

is further detailed in the experimental examples for specific assays that can be used to generate output data. For example, in Example 1, page 15, "Evaluation of test results," the assay was carried out on an active TB sample, where, in Table 5, the T-lymphocyte response to the peptide composition of claim 37 (measured in this case by ELISPOT on PBMC) is reported in Row 4. This response is higher than the control response (see Row 1: CTR or DMSO) and is comparable to the response induced by CFP-10 or ESAT-6 whole proteins (RD1 proteins: commercial antigens). In Table 6 the absolute values calculated by subtracting results obtained for the whole protein (RD1 proteins) is reported, as compared to those achieved for the peptide composition, and are both positive (+) and to be interpreted according to Table 3, page 11 (see last row, 3rd and 4th columns) to be related to an active TB infection or a recent TB infection or TB re-infection (see Table 3, last row, last column "STATUS"). Calculations according to the same criteria were carried out on samples with different TB conditions in different examples in the experimental part. The values obtained are compared with control values, in order to determine whether the test sample presents a positive or a negative response. Further support for step ii) is found, for example, at page 10, lines 4-6, and at page 12, 3rd paragraph:

> To define the status of the patient, it is necessary to quantify the output of the responses (output is, for example for ELISPOT, the number of SFCs). As explained above, the absolute value is determined by subtracting the control output from the row number. Scoring procedures are then performed as indicated above. The results are then analyzed to determine the status of tuberculosis as explained in Table 3. Such a process is highly suited to a computer program and the logic behind any such software is represented in Fig. 9.

Step iii) of claim 39 concerns correlating the results (T-lymphocyte response) with the TB status in order to provide a diagnostic indication. Support for step iii) is found, for example, in Table 3 at page 11, and on the same page, below the table, in the paragraph entitled

"Interpretation criteria of the results," points i) and ii).

New dependent claims 57 and 58 have been added, which are supported by prior claims 48 and 40, respectively.

New kit claims (claim 59 and 60) have also been added, which specify the peptides of claims 37 and 38. Support for this claim can be found in prior claim 55, as well as in claims 37 and 38.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. Transmitted herewith is a Petition to extend the period for replying to the Office Action for one month, to and including December 21, 2009, and payment of the required extension fee. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: December 4, 2009

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